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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,791	03/09/2008	Marc Kuttler	149459-110070	1489

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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
03/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-at@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,791	KUTTLER ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This action is in response to remarks and amendments filed January 6, 2011. No claims were canceled or withdrawn. Claims 1 and 6 were amended. Claims 7-11 were newly added; support is found in the specification as filed for the newly added claims and amendments. Accordingly, claims 1-11 are pending in the application.

Withdrawn Claim Objections and Rejections

The objection to claim 6 under 37 CFR 1.75(c) as being of improper dependent form is withdrawn in light of Applicant's amendments to the claims filed 1/6/2011.

The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Tormala (WO 97/11724) is withdrawn in light of Applicant's amendments to the claims filed 1/6/2011.

The provisional double patenting rejection of claims 1-6 over claim 1 of co-pending Application No. 10/562,376 is withdrawn.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. Claims 7 and 8 recite a material which is “WE43”, however the specification as filed does not define this material and the skilled artisan would not have been reasonably apprised of the chemical composition thereof. Even if "WE43" is a commonly recognized material, it is not clear that chemical make-up of the material is constant from one manufacturer and a time to another, therefore, it is indefinite exactly what material is being included in the claims.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites that each material is disposed… “at either different locations or as multilayer systems at specific distinct locations on the main body”. It is unclear what structural configuration is being described; it is unclear what the critical features of this configuration actually are. In particular, it is unclear what locations would constitute being "specific". The meaning of the term "specific" is vague and does not appear to contribute any structural or functional limitations into the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala (WO 97/11724, published April 3, 1997, submitted in IDS of 7/13/2006) in view of Steinke (US 2002/0103526 A1, published August 1, 2002).

Tormala teaches a biodegradable device for tissue implanting manufactured of polymeric material; the biodegradable device is employed as a tubular configuration (see page 2, line 30 – page 3, line 19; see abstract). The device comprises two or more zones created such that the biodegradable polymeric material has different degradation properties in each of the different zones (see page 3, lines 11-15 and 28-30). Tormala teaches that an elongated implant device disintegrates in a controlled manner under hydrolytic conditions into small particles at its different parts at different times (see page 4, lines 18-24). Specifically, Tormala teaches that creating the device to have walls of different thickness at different parts allows control of the different disintegration of

parts (see page 4, lines 26-31); this teaching is construed to be at least a material modification of the material as in pending claim 2.

The claim term "predefined" in claims 1, 5, and 6 is considered to indicate that a given property (a predefined property) is inherent in the materials required by the claim. For example, the devices of Tormala are made of substances in amounts and depositions that convey predefined degradation characteristics that will vary with pathophysiological and rheological conditions. Absent evidence that the degradation or flow characteristics will vary, it is reasonable to expect that deformation of an object or flow of a liquid will cause stress on the object/liquid and therefore affect the rate at which it degrades. The selection of materials, result-effective variables, having the desired degradation parameters would have been within the skill or the ordinary artisan to optimize based on the teachings of the cited references.

The teaching of Tormala is directed to polymeric based biodegradable implant materials rather than a metallic alloy material as required by claim 1.

However, Steinke teaches biodegradable stents and their protective coatings for biomedical applications (see abstract, in particular). Steinke teaches that the tubular member of the stent is comprised of and coated with a degradable material. The stent comprises at least two modules wherein the expanded diameters of the first and second modules are different (see [0029] and [0035]). The stent may be made of a polymer, a metal, a ceramic, or combinations thereof, and may be degradable (see [0032]). Regarding claim 7, magnesium alloys are included among the acceptable and explicitly disclosed

degradable stent materials (see [0037]). The stents include coatings which preferably are degradable (see [0044]). Further regarding claim 9, poly lactic acid (also known as polylactide) is named as a particular slowly degrading polymer which is equivalent to PHV/PHB (i.e., polyhydroxybutyrate/polyhydroxyvalerate copolymers) (see [0041]); it is noted that Tormala also teaches polylactide copolymers to have been successful (see Example 6, page 13, lines 35-37). It is noted that PHB and PHV and copolymers thereof are recited in pending claim 9. Further regarding the coating as in claim 8, tyrosine polyarylates are taught as acceptable coatings (see [0041]) and acceptable stent materials (see [0037]); therefore, as to claim 8, it would have been obvious to substitute a magnesium alloy in not only the stent material as iterated above but also in the biodegradable coating material, with a reasonable expectation of success. See MPEP 2144.06 (II) regarding the obviousness of substituting known equivalents for the same purpose.

Both Tormala and Steinke are directed to biodegradable stent devices for biomedical applications. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize a magnesium alloy in the stent and/or coating material as well as a polylactide material in the stent coating, based on the obviousness of equivalents as disclosed in the Steinke reference, with a reasonable expectation of success. Regarding claim 10, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize the polymeric and/or metallic materials taught by Steinke in combination as in the teaching of Tormala, with a

reasonable expectation of success. One would have been motivated to do so since Tormala teaches that different zones of an implant are created by having different materials and structures and that this is desirable since it facilitates controlled degradation for each segment. For instance, a rod-like perform or a spiral structured tube having tubular braiding comprised of different materials facilitates controlled disintegration and therefore release of each active agent (see page 3 of Tormala and page 4, lines 26-36). Based on Steinke's teaching of various degrading polymers including those which degrade relatively slowly, one of ordinary skill in the art at the time the invention was made reasonably would have expected continued success from substituting stent and polymeric coating materials as taught by Steinke in the devices of Tormala (see [0041] of Steinke).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala (WO 97/11724, published April 3, 1997, submitted in IDS of 7/13/2006) in view of Steinke (US 2002/0103526 A1, published August 1, 2002) as applied to claims 1-7, 9, and 10 above, and further in view of Andersen (US 5,360,440, issued Nov. 1, 1994).

The teachings of Tormala and Steinke are delineated above. Although Steinke teaches that materials such as magnesium may be included in a stent material, motivation for implementing one of the instantly recited materials (magnesium, iron, tungsten, WE43) into a stent coating is not clearly and explicitly set forth in the Steinke reference.

However, Andersen teaches an *in situ* stent apparatus for generating an electrical current in a biological environment in order to impede certain cell growth; these stent devices include anode and cathode layers which act to generate an electrical current upon contact with an electrolyte (see column 1, lines 7-11; column 3, lines 2-30). For example, the stent assembly (see Figure 2) has the general form of an open ended, closed wall structure and includes, as nested or concentric elements, an inner stent, an intermediate insulator, and an outer stent that form a three-layer cylindrical structure in one embodiment (see column 4, lines 45-59). It is the Examiner's position that these layers on top of the basic stent structure constitute coatings. Andersen specifies that either the inner stent or the outer stent acts as a cathode [and the other the anode] (see column 5, lines 8-10). The anode material is selected to have an acceptable life expectancy, with iron being a preferred anode material (see column 5, lines 23-35).

Both Anderson and Steinke are directed to stents coated with layers of variable, controlled life expectancy and degradation characteristics. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize iron as the anode in the anode-cathode coatings of Andersen and to implement the anode-cathode features as taught by Andersen into the teachings of Tormala and Steinke, with a reasonable expectation of success. One would have been motivated to do so to desirably impede cell growth surrounding the stent implant device, as taught by Anderson.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala (WO 97/11724, published April 3, 1997, submitted in IDS of 7/13/2006) in view of Steinke (US 2002/0103526 A1, published August 1, 2002) as applied to claims 1-7, 9, and 10 above, and further in view of Pinchuk (US 5,575,818, issued November 19, 1996).

The teachings of Tormala and Steinke are delineated above. Although both are directed to stents implemented into the tissue to facilitate regrowth, a circumstance which likely required in the surface (coating) of the stent, it is not explicitly clear that porosity of the stent coating was required, as recited in claim 11.

Pinchuk teaches stent coating materials which are dissolvable or degradable (see column 5, lines 15-18 and column 8, lines 47-50). These coatings preferably are of a porous material to form an endovascular graft (see column 4, lines 54-56).

Since Tormala, Steinke, and Pinchuk are all directed to biodegradable stent coating materials, it would have been *prima facie* obvious to on of ordinary skill in the art at the time the invention was made to utilize a porous coating in particular, with a reasonable expectation of success. One would have been motivated to do so since Pinchuk teaches that in an endovascular graft, the stent is coated with a porous bio-compatible material which facilitates tissue ingrowth throughout the length of the stent (see column 5, lines 9-13).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 provisionally are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/562,376 in view of Steinke (US 2002/0103526 A1, published August 1, 2002).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a tubular bodied implant device (i.e., stent) having multiple coatings each having its own characteristic release rate. The characteristic release rate (i.e., degradation characteristic) facilitates controlled release of an active or formulation component

into the tissue surrounding the tubular device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the release rate of an active agent from a carrier or coating in or on a stent or endovascular implant device. One would have been motivated to do so to maximize pharmaceutical efficacy and to minimize waste of the drug.

The copending claims do not specify a metallic alloy in the tubular body of the implant/stent device, however Steinke teaches biodegradable stents and their protective coatings for biomedical applications (see abstract, in particular). Steinke teaches that the tubular member of the stent is comprised of and coated with a degradable material. The stent comprises at least two modules wherein the expanded diameters of the first and second modules are different (see [0029] and [0035]). The stent may be made of a polymer, a metal, a ceramic, or combinations thereof, and may be degradable (see [0032]). Magnesium alloys are included among the acceptable and explicitly disclosed degradable stent materials (see [0037]) which were equivalent to the stent materials disclosed in the embodiments of the Steinke reference.

Both the copending claims and the Steinke reference are directed to stent devices for biomedical applications. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize a magnesium alloy in the stent and/or coating material, based on the disclosure of the Steinke reference, with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments presented January 6, 2011 have been fully considered but are not persuasive in light of amendments. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Applicant argues that the instant invention is different from the Tormala reference since the instant invention has a main body made of a metallic alloy. Applicant argues that this alleged difference solves the problem of undesired implant fragmentation and that metal bodies differ from polymeric bodies with respect to dilatation state and degradation. Applicant argues that the instant invention can degrade at different places simultaneously. Finally, Applicant argues that the Tormala reference is not suitable for solving the "addressed problem" because Tormala has one or more zones of coating with one predefined degradation curve and relates to a base body having one thickness. Applicant chooses not to respond to the double patenting rejection at this time.

In reply, Applicant's arguments have been considered but are not persuasive. The "metal alloy" limitation has been addressed above as necessitated by amendment. Based on the rejection of record, there is no evidence in the record that a polymer coated metallic device would produce unsatisfactory results since the arguments of counsel cannot take the place of evidence in the record. See *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716,

718 (CCPA 1965). Regarding Applicant's argument that Tormala has one or more zones of coating with a predefined degradation curve, this teaching has been cited for what it reasonably would have suggested to one of ordinary skill in the art at the time the invention was made. It is maintained that one of ordinary skill in the art would have been able to apply the teachings of Tormala and Steinke in order to control the degradation rate of both the tubular body and the coating, and it is apparent from these teachings that the coating would have degraded prior to the stent in order, for example, to facilitate tissue ingrowth. As such, Applicant's arguments are not persuasive.

Conclusion

No claims are found allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635